

Summary of the Office Action of November 14, 2002

In the Office Action mailed March 28, 2002, the Examiner objected to Figure 5. The Examiner also rejected claims 16-19 under 35 U.S.C. § 112, first paragraph. The Examiner further rejected claims 16-19 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,293,951 (the '951 patent) to Alferness et al. Furthermore, claims 16-19 were rejected under 35 U.S.C. § 102(f).

Applicants respectfully request reconsideration of the application in light of the following comments.

Objection to the Drawings

The Examiner objected to Figure 5, stating that there are two reference numbers "34". Applicants have submitted herewith a proposed drawing correction of Figure 5 with revisions to Figure 5 shown in red ink. Figure 5 has been revised to replace the uppermost reference numeral "34" with "30". Applicants respectfully submit that the revised Figure 5 overcomes the Examiner's objection.

Rejection under 35 U.S.C. § 112

The Examiner rejected claims 16-19 under 35 U.S.C. § 112, first paragraph. According to the Examiner, claims 16-19 contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the invention. The Examiner stated that there is no support in the specification for a bronchial sub-branch obstruction device for reducing the size of a lung with all the required structural

elements or a conduit configured to be passed down a trachea. According to the Examiner, the current invention is a body fluid control device for urinary, venous or pulmonic placement.

Applicants submit that the written description provides more than adequate support for all of the elements of claims 16-19. Applicants submit herewith charts (contained in Appendix A) that set forth exemplary sections of the specification that provide support for each of claims 16-19. For each claim, the charts include a first column that recites the claim element and a second column that cites the sections of the specification that support the corresponding claim element. As shown in exemplary text contained in the attached chart, the written description provides support for an obstruction device having all of the structural limitations of the claims. Regarding the functional language contained in the claims, an obstruction device having the recited structural limitations would inherently possess the claimed functionality. In such a circumstance, the functional language does not carry any patentable weight. *See generally In re Schreiber*, 128 F.3d 1473 (Fed. Cir. 1997).

Notwithstanding that the lung-related functional language does not carry patentable weight, the written description of the instant application indeed provides support for using the disclosed device in connection with the lung. Specifically, the Summary (at page 3, lines 4-6) states that "it is a principal object of the present invention to provide a flow control device for the human body such as for ... pulmonic placement." According to the Merriam-Webster dictionary, the word "pulmonary" means "relating to, functioning like, or associated with the lungs." Thus, the written description of the instant application provides support for placing the device in a lung passageway.

Rejection Under 35 U.S.C. § 102(e)

The Examiner rejected claims 16-19 under 35 U.S.C. §102(e) as being anticipated by the '951 patent, which has a filing date of August 24, 1999. However, Applicants respectfully submit that the '951 patent does not qualify as prior art to the instant application under 35 U.S.C. §102(e), as the instant application has an effective filing date that precedes the filing date of the '951 patent. The instant application is a continuation of U.S. Patent Application Serial No. 09/397,218, filed September 16, 1999, which is a continuation of U.S. Patent Application Serial No. 08/931,552, filed September 16, 1997, issued as U.S. Patent No. 5,954,766. Thus, the effective filing date of the instant application is September 16, 1997. The filing date of the '951 patent is almost two years after the effective filing date of the instant application.

Thus, the '951 patent is not "a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent", as required by 35 U.S.C. §102(e). Accordingly, Applicants respectfully submit that the rejection under 35 U.S.C. §102(e) should be withdrawn.

Rejection Under 35 U.S.C. § 102(f)

Claims 16-19 stand rejected under 35 U.S.C. §102(f). According to the Examiner, the applicant did not invent the claimed subject matter because claims 16-19 were copied from the '951 patent. Applicants submit that the subject matter of claims 16-19 was invented by Applicants and that an interference should be declared between the instant application and the '951

Request for Reconsideration
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U.S.S.N. 10/081,569

patent, as set forth in the Request for Interference that will be filed in connection with the instant application.

If the Examiner has any questions regarding the foregoing, she is cordially invited to contact the undersigned so that any such matters may be promptly resolved.

Respectfully submitted,
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APPENDIX A - Exemplary Support for Claims

Claim 16 of the '569 application	Disclosure of '569 application
A bronchial sub-branch obstruction device for reducing the size of a lung comprising	<p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>
an obstructing member dimensioned for insertion into a bronchial sub-branch communicating with a portion of the lung to be reduced in size,	<p>p.6, lines 6-8 "In the expanded state, the overall device is intended to fit with interference with the duct or passageway. Before expansion, easy insertion is contemplated with clearance."</p> <p>p.7, lines 5-6 "...the outside diameter of the resilient seal 20 is approximately .349 [inches]."</p> <p>p.7, lines 7-9 "The frame is cylindrical with an OD in the insertion state of approximately .329[inches], a length of approximately .304[inches] and a thickness of approximately .005[inches] to .015[inches]."</p>
the obstructing member having an outer dimension which is so dimensioned as to make continuous contact with an inner dimension of the bronchial sub-branch to seal the bronchial sub-branch upon placement in the bronchial sub-branch, to preclude normal function of the lung portion, and to collapse the portion of the lung for reducing the size of the lung,	<p>p.6, lines 6-7 "In the expanded state, the overall device is intended to fit with interference with the duct or passageway."</p> <p>p.7, lines 7-9 "The frame is cylindrical with an OD in the insertion state of approximately .329[inches], a length of approximately .304[inches] and a thickness of approximately .005[inches] to .015[inches]."</p> <p>p.4, lines 3-6 "The device includes a resilient seal 20 which, in this first embodiment, includes a cylindrical elastomeric or, more generally, polymeric material capable of sealing within the interior of a body duct or</p>

	<p>passageway."</p> <p>p. 4, lines 8-9 "[T]he seal has a substantially circular cross-section to fit within the body duct or passageway."</p> <p>p.7, lines 5-6 "...the outside diameter of the resilient seal 20 is approximately .349 [inches]."</p>
<p>wherein the obstructing member is a one-way valve to permit exhaled air to flow from the lung portion while precluding inhaled air from flowing into the lung portion.</p>	<p>p.4, lines 2-3 "Figures 1 and 2 illustrate a first fluid flow control device capable of one-way flow..."</p> <p>p. 5, line 5 "The valve body 24 acts in this embodiment as a one-way valve...."</p> <p>p.16, line 5 "One-way valve operation may be provided..."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>

Claim 17 of the '569 application	Disclosure of '569 application
<p>A bronchial sub-branch obstruction system for reducing the size of a lung comprising:</p>	<p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>
<p>a conduit configured to be passed down a trachea, into a bronchus communicating with the trachea, and into a bronchial sub-branch communicating the bronchus with a lung portion to be reduced in size; and</p>	<p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p.11, lines 12-14 "Another mechanism for providing an elongate expander and insertion tool is</p>

	illustrated in Figure 12. The device includes an outer sheath 88 into which is positioned a fluid flow control device ..."
an obstructing member so dimensioned as to be guidable through the conduit and placed in the bronchial sub-branch to seal the bronchial sub-branch, to preclude normal function of the lung portion, and to collapse the lung portion,	<p>p.11, lines 12-14 "Another mechanism for providing an elongate expander and insertion tool is illustrated in Figure 12. The device includes an outer sheath 88 into which is positioned a fluid flow control device ..."</p> <p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p. 2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>
wherein the obstructing member is a one-way valve to permit exhaled air to flow from the lung portion while precluding inhaled air from flowing into the lung portion.	<p>p.4, lines 2-3 "... a first fluid flow control device capable of one-way flow..."</p> <p>p. 5, line 5 "The valve body 24 acts in this embodiment as a one-way valve...."</p> <p>p.16, line 5 "One-way valve operation may be provided..."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>

Claim 18 of the '569 application	Disclosure of '569 application
A bronchial sub-branch obstruction device for reducing the size of a lung comprising	<p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>
an obstructing member dimensioned for insertion into a bronchial sub-branch communicating with a portion of the lung to be reduced in size,	<p>p.6, lines 6-8 "In the expanded state, the overall device is intended to fit with interference with the duct or passageway. Before expansion, easy insertion is contemplated with clearance."</p> <p>p.7, lines 5-6 "...the outside diameter of the resilient seal 20 is approximately .349 [inches]."</p> <p>p.7, lines 7-9 "The frame is cylindrical with an OD in the insertion state of approximately .329[inches], a length of approximately .304[inches] and a thickness of approximately .005[inches] to .015[inches]."</p>
the obstructing member having an outer dimension which is so dimensioned as to make continuous contact with an inner dimension of the bronchial sub-branch to seal the bronchial sub-branch upon placement in the bronchial sub-branch to preclude air from being exhaled from the lung portion and inhaled into the lung portion for collapsing the portion of the lung and reducing the size of the lung,	<p>p.6, lines 6-7 "In the expanded state, the overall device is intended to fit with interference with the duct or passageway."</p> <p>p.7, lines 7-9 "The frame is cylindrical with an OD in the insertion state of approximately .329[inches], a length of approximately .304[inches] and a thickness of approximately .005[inches] to .015[inches]."</p> <p>p.4, lines 3-6 "The device includes a resilient seal 20 which, in this first embodiment, includes a cylindrical elastomeric or, more generally, polymeric material capable of sealing within the interior of a body duct or passageway."</p>

	<p>p. 4, lines 8-9 "[T]he seal has a substantially circular cross-section to fit within the body duct or passageway."</p> <p>p.7, lines 5-6 "...the outside diameter of the resilient seal 20 is approximately .349 [inches]"</p>
<p>wherein the obstructing member is a one-way valve to permit exhaled air to flow from the lung portion while precluding inhaled air from flowing into the lung portion.</p>	<p>p.4, lines 2-3 "... a first fluid flow control device capable of one-way flow..."</p> <p>p. 5, line 5 "The valve body 24 acts in this embodiment as a one-way valve...."</p> <p>p.16, line 5 "One-way valve operation may be provided..."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>

Claim 19 of the '569 application	Disclosure of '569 application
<p>A bronchial sub-branch obstruction system for reducing the size of a lung comprising:</p>	<p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>
<p>a conduit configured to be passed down a trachea, into a bronchus communicating with the trachea, and into a bronchial sub-branch communicating the bronchus with a lung portion to be reduced in size; and</p>	<p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p. 11, lines 12-14 "Another mechanism for providing an elongate expander and insertion tool is illustrated in Figure 12. The device</p>

	includes an outer sheath 88 into which is positioned a fluid flow control device ..."
an obstructing member so dimensioned as to be guidable through the conduit and placed in the bronchial sub-branch to seal the bronchial sub-branch to preclude air from being exhaled from the lung portion and inhaled into the lung portion and to collapse the lung portion,	<p>p.11, lines 12-14 "Another mechanism for providing an elongate expander and insertion tool is illustrated in Figure 12. The device includes an outer sheath 88 into which is positioned a fluid flow control device ..."</p> <p>p.3, lines 4-6 "...a flow control device for the human body such as for ...pulmonic placement."</p> <p>p.2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>
wherein the obstructing member is a one-way valve to permit exhaled air to flow from the lung portion while precluding inhaled air from flowing into the lung portion.	<p>p.4, lines 2-3 "... a first fluid flow control device capable of one-way flow..."</p> <p>p. 5, line 5 "The valve body 24 acts in this embodiment as a one-way valve...."</p> <p>p.16, line 5 "One-way valve operation may be provided..."</p> <p>p. 2, lines 13-16 "a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of ... a one-way flow restriction."</p>